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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/526,940 | 10/21/2005 | Ulrich Deuschle | BB-137 | 7569 |

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| EXAMINER | |
|---|---|
| CHENG, KAREN | |
| ART UNIT | PAPER NUMBER |
| 1626 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 31 DAYS | 01/22/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/526,940 | DEUSCHLE ET AL. | |
| | Examiner | Art Unit | |
| | Karen Cheng | 1626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-27 are currently pending in the instant application and subject to the following restriction requirement.

### *Lack of Unity Requirement*

Claims 1-27 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision set forth in PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). PCT Rule 13.2 further states unity of invention as referred to in PCT Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. Special technical features, as defined in PCT Annex B, Part 1(b), include those technical features which define a contribution over the prior art.

PCT Annex B, Part 1(e) provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Due to numerous and widely divergent variables in the compound of Formula (I) for example: **$R_1$, $R_2$, $R_3$, $R_4$, $R_5$** a precise listing of inventive groups cannot be made. The following Groups are exemplary:

Group I: Claims 1-4 (in part), 7-8 (in part), 27 (in part) drawn to a compound of formula (1), pharmaceutical acceptable salts or solvates thereof and a pharmaceutical composition wherein

$R_1$ is phenyl, substituted phenyl, napthyl or substituted napthyl
$R_2$ is H, $C_1$ to $C_8$ alkyl, $C_1$ to $C_7$ acyl, $C_1$ to $C_7$ substituted acyl, $C_1$ to $C_8$ substituted alkyl, $C_7$ to $C_{12}$ alkylphenyl, $C_7$ to $C_{12}$ substituted alkylphenyl, $C_7$ to $C_{12}$ substituted phenylalkyl, $C_3$ to $C_8$ cycloalkyl, or $C_3$ to $C_8$ substituted cycloalkyl
$R_3$ is H, $C_1$ to $C_8$ alkyl, $C_1$ to $C_8$ substituted alkyl, $C_7$ to $C_{12}$ alkyl phenyl, $C_7$ to $C_{12}$ substituted alkyl phenyl, halogen, $C_1$ to $C_8$ alkoxy, carboxy, amide or $C_1$ to $C_8$ aminoacyl,
$R_4$, $R_5$ and $R_6$ are as defined.

Group II: Claims 1-4 (in part), 7-8 (in part), 27 (in part) drawn to a compound of formula (1), pharmaceutical acceptable salts or solvates thereof and a pharmaceutical composition wherein

$R_1$ is $C_5$ to $C_6$ heteroaryl, $C_5$ to $C_6$ substituted heteroaryl

$R_2$ is $C_5$ to $C_6$ heteroaryl or [$C_5$ to $C_6$]-heteroaryl-($C_1$ to $C_6$)-alkyl
$R_3$ is H, $C_1$ to $C_8$ alkyl, $C_1$ to $C_8$ substituted alkyl, $C_7$ to $C_{12}$ alkyl phenyl, $C_7$ to $C_{12}$ substituted alkyl phenyl, halogen, $C_1$ to $C_8$ alkoxy, carboxy, amide or $C_1$ to $C_8$ aminoacyl.
$R_4$, $R_5$ and $R_6$ are as defined.

Group III: Claims 1-4 (in part), 5, 7-8 (in part), 27 (in part) drawn to a compound of formula (1), pharmaceutical acceptable salts or solvates thereof and a pharmaceutical composition wherein

$R_1$ is phenyl, substituted phenyl, napthyl or substituted napthyl
$R_2$ is H, $C_1$ to $C_8$ alkyl, $C_1$ to $C_7$ acyl, $C_1$ to $C_7$ substituted acyl, $C_1$ to $C_8$ substituted alkyl, $C_7$ to $C_{12}$ alkylphenyl, $C_7$ to $C_{12}$ substituted alkylphenyl, $C_7$ to $C_{12}$ substituted phenylalkyl, $C_3$ to $C_8$ cycloalkyl, or $C_3$ to $C_8$ substituted cycloalkyl
$R_3$ is furanyl or substituted furanyl
$R_4$, $R_5$ and $R_6$ are as defined.

Group IV: Claims 1-4 (in part), 6, 7-8 (in part), 27 (in part) drawn to a compound of formula (1), pharmaceutical acceptable salts or solvates thereof and a pharmaceutical composition wherein

$R_1$ is phenyl, substituted phenyl, napthyl or substituted napthyl
$R_2$ is H, $C_1$ to $C_8$ alkyl, $C_1$ to $C_7$ acyl, $C_1$ to $C_7$ substituted acyl, $C_1$ to $C_8$ substituted alkyl, $C_7$ to $C_{12}$ alkylphenyl, $C_7$ to $C_{12}$ substituted alkylphenyl, $C_7$ to $C_{12}$ substituted phenylalkyl, $C_3$ to $C_8$ cycloalkyl, or $C_3$ to $C_8$ substituted cycloalkyl
$R_3$ is thiazyl or substituted thiazyl
$R_4$, $R_5$ and $R_6$ are as defined.

Group V: Claims 9-11 and 15-17 drawn to a method of use selected from: prevention or treatment of a NR3B1 receptor protein or NR3B1 receptor protein mediated disease

such as treating a disease affected by estrogen levels, cancer, osteoporosis, obesity, lipid disorders, etc wherein by administration of a compound wherein

$R_1$ is phenyl, substituted phenyl, napthyl or substituted napthyl
$R_2$ is H, $C_1$ to $C_8$ alkyl, $C_1$ to $C_7$ acyl, $C_1$ to $C_7$ substituted acyl, $C_1$ to $C_8$ substituted alkyl, $C_7$ to $C_{12}$ alkylphenyl, $C_7$ to $C_{12}$ substituted alkylphenyl, $C_7$ to $C_{12}$ substituted phenylalkyl, $C_3$ to $C_8$ cycloalkyl, or $C_3$ to $C_8$ substituted cycloalkyl
$R_3$ is H, $C_1$ to $C_8$ alkyl, $C_1$ to $C_8$ substituted alkyl, $C_7$ to $C_{12}$ alkyl phenyl, $C_7$ to $C_{12}$ substituted alkyl phenyl, halogen, $C_1$ to $C_8$ alkoxy, carboxy, amide or $C_1$ to $C_8$ aminoacyl,
$R_4$, $R_5$ and $R_6$ are as defined.

Group VI: Claims 9-11 and 15-17 drawn to a method of use selected from: prevention or treatment of a NR3B1 receptor protein or NR3B1 receptor protein mediated disease such as treating a disease affected by estrogen levels, cancer, osteoporosis, obesity, lipid disorders, etc wherein by administration of a compound wherein

$R_1$ is $C_5$ to $C_6$ heteroaryl, $C_5$ to $C_6$ substituted heteroaryl
$R_2$ is $C_5$ to $C_6$ heteroaryl or [$C_5$ to $C_6$]-heteroaryl-($C_1$ to $C_6$)-alkyl
$R_3$ is H, $C_1$ to $C_8$ alkyl, $C_1$ to $C_8$ substituted alkyl, $C_7$ to $C_{12}$ alkyl phenyl, $C_7$ to $C_{12}$ substituted alkyl phenyl, halogen, $C_1$ to $C_8$ alkoxy, carboxy, amide or $C_1$ to $C_8$ aminoacyl.
$R_4$, $R_5$ and $R_6$ are as defined.

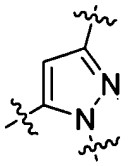
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again this list is not exhaustive as it would be impossible to write out all groups under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product or a process of preparation or a method of

use) by identifying another specific embodiment of similar scope not listed in the exemplary groups of the invention and examiner will endeavor to group the same. The applicant may also choose to elect a single disclosed species or a single disclosed species for a single method of use or preparation and the examiner will endeavor to create a group comprising the elected species.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 since under 37 CFR 1.475:

> Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features. . .those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

**Groups I-VI** lack unity of invention because, pursuant to 37 CFR 1.475(a), the structural moiety common to **Groups I-VI** is a substituted pyrazole




This technical feature is not a special technical feature because it fails to define a contribution over the prior art (*see* Journal of Medicinal Chemistry (1995), 38(4), 617-28, compound 13). Therefore, Claims 1-27 are not so linked as to form a single general inventive concept, and there is lack of unity of invention. The variables vary extensively and, when taken as a whole, result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the

claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product, a process for the manufacture of said product, ***or*** a method of use.

Furthermore, with respect to **Groups I-VI**, even if unity of invention under 36 CFR 1.475(a) is not lacking, a national stage application, under 37 CFR 1.475(b), containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to only one of the following combinations:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of said product, and a use of said product; or
(4) A process and an apparatus or means specially designed for carrying out said process; or
(5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specially designed for carrying out said process.

Moreover, according to 37 CFR 1.475(c), if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case, the claims are drawn to multiple products and more than one process of use of said product. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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